I. Certified Priority Documents

The Examiner reports that the certified priority documents were not received. Included in this amendment is a copy of the certificates of true copies for GB 0007112.6 filed 3/23/00 and GB 0010846.4 filed 5/3/00 and the transmittal page, all of which were filed with the USPTO with Express Mail No. EL625564888US. However, to facilitate processing of this procedural matter, we are ordering another set of certified priority documents for GB 0007112.6 and GB 0010846.4 and will mail those certified copies to the USPTO upon receipt.

II. Claim Rejections Under 35 U.S.C. § 103(a)

The Examiner rejects claims 1-11 under 35 U.S.C. § 103(a) as allegedly unpatentable over U.S. Patent No. 4,428,927 to Ebert et al ("Ebert"). This rejection is respectfully traversed.

The present application is directed to oral formulations that include a solid masticable portion consisting of a digestible material. The present invention also is directed to methods of treatment with such formulations.

In contrast, Ebert discloses chewable formulations that include 1-75% of an insoluble masticatory substance. Col. 2, lines 31-41. Such insoluble materials are essential to Ebert in solving the problem of capsules that generally dissolve "rapidly in the mouth, thereby leaving little or no residue for further chewing." Col. 1, lines 41-45. As such, Ebert teaches that a chewable product should "leave a chewable, insoluble residue in the mouth and this residue should not change significantly in size upon continued chewing; at all times, the insoluble residue should retain a generally normal chewing texture or consistency." Col. 1, lines 45-51.

Applicants contend that the amended claims are not *prima facie* obvious in view of Ebert. The Board of Patent Appeals and Interferences has stated that "to establish a *prima facie* case of obviousness, it is necessary for the examiner to present evidence, preferably in the form of some teaching, suggestion, incentive or inference in the applied prior art, or in the form of generally available knowledge, that one having ordinary skill in the art would have been led to combine the relevant teachings of the applied references in the proposed manner to arrive at the claimed invention." Ex parte Levengood, 28 U.S.P.Q.2d 1300, 1301 (BOPAI 1993). Not only must there be evidence of motivation, but also, the skilled worker must have an expectation that the modified teachings would be successful. Ebert fails to meet these requirements.

Given the claim amendment, a skilled worker would have to be motivated to modify Ebert's formulation from one containing an insoluble material to one that consists of a digestible material. It is well known that digestion requires at least partially soluble materials, materials

that are capable of being assimilated into the body. As such, a skilled worker would not be motivated to modify Ebert's formulations to include digestible materials because Ebert teaches away from using formulations consisting of digestible products by stating that chewables should leave an insoluble residue in the mouth. Given this teaching, a skilled worker would not expect formulations consisting of digestible materials to be successful. As a result, Applicants respectfully request withdrawl of this rejection.

Applicants believe that further and favorable action in the form of a Notice of Allowance Issue is next in order, and such action is earnestly solicited.

Should the Examiner have any questions or comments regarding this amendment or the application in general, he is invited to call the undersigned at (860) 686-0349.

A petition for a two month extension of time is included herewith; as such, the Commissioner is hereby authorized to charge the two month extension of time fee, and any other fees that may be required, or credit any overpayment, to Deposit Account No. 16-1445.

Respectfully submitted,
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Exhibit A

MARKED UP CLAIMS

(strike-through denotes deleted text and underline denotes added text)

1. (Once Amended) An oral formulation for a medicament comprising:

a solid masticable portion and one or more reservoir portions encompassed by said solid masticable portion;

the solid masticable portion consisting of a ~~fully edible~~ digestible material, having a Young's modulus of 0.01-5Mpa, and compressive strength in the range 10-10,000 mJ,

the reservoir portion or portions comprising a releasable dose of the medicament in a fluid ~~(preferably a liquid)~~ form, with a viscosity below 800 mPas at body temperature ~~(ca. 36- ca. 40°C)~~,

such that on mastication, the masticable portion is ruptured and the unit dose of the medicament is released in a short space of time from the reservoir portion into the oral cavity.

3. (Once amended) A formulation according to claim 1, which consists of:

a masticable portion containing gelatine ~~(about 20%)~~, gum Arabic ~~(about 3%)~~, ~~pork liver powder and/or beff powder as~~ flavourant, ~~each at about 6%,~~ in a hydrogenated polysaccharide ~~Lycasin®~~ base;

a reservoir portion comprising ~~Lycasin®~~ hydrogenated polysaccharide base, malt flavouring ~~(about 1%) by weight~~ and the medicament.

4. (Once amended) A formulation according to ~~any previous~~ claim 1 wherein the reservoir portion is up to 40% by volume of the formulation.

6. (Once amended) A formulation according to ~~any previous~~ claim 1 wherein the shape of the formulation is substantially hemispherical.

7. (Once amended) A formulation according to claim 1 wherein the masticable portion contains about 20% gelatine ~~(at about 20%)~~, about 3% gum Arabic ~~(at about 3%)~~, ~~and flavourants:~~ about 6% pork liver powder ~~and~~ , about 6% beef powder, in a hydrogenated polysaccharide ~~Lycasin®~~ base;

and the reservoir portion comprises ~~Lycasin®~~ hydrogenated polysaccharide base, about 1% malt flavouring ~~(at about 1%) by weight~~, and the medicament.

8. (Once amended) A formulation according to ~~any previous~~ claim 1 wherein the medicament is present at up to about 3% by weight.

11. (Once amended) A method of treatment to reduce plaque, control gingivitis, prevent calculus, prevent halitosis, or prevent periodontitis in a human or non-human animal subject in need of treatment with a medicament comprising administration of a formulation of said medicament according to ~~any previous~~ claim any one of claims 1 to 8.